

# **Patent and Trademark Office**

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ATTORNEY DOCKET NO. FIRST NAMED INVENTOR APPLICATION NO. FILING DATE P1101P1 **ASHKENAZI** 02/09/98 09/020,746 **EXAMINER** HM22/0526 KAUFMAN, C GENENTECH INC ART UNIT PAPER NUMBER DIANE L MARSCHANG 1 DNA WAY 1646 SOUTH SAN FRANCISCO CA 94080-4990

DATE MAILED:

05/26/99

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

	Application No.	Applicant(s)
Office Action Summary	09/020,746	ASHKENAZI, ET AL.
	Examiner	Art Unit
	Claire M. Kaulman	1646
The MAILING DATE of this communication appe	· ·	
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.		
<ul> <li>Extensions of time may be available under the provisions of 37 of after SIX (6) MONTHS from the mailing date of this community.</li> <li>If the period for reply specified above is less than thirty (30) day be considered timely.</li> <li>If NO period for reply is specified above, the maximum statutory communication.</li> <li>Fallure to reply within the set or extended period for reply with, breather than the set of extended period for reply with the set or extende</li></ul>	cetion. s, a reply within the statutory minim y period will apply and will expire SI)	num of thirty (30) days will X (6) MONTHS from the mailing date of this
<ul> <li>Fallure to reply within the set or extended period for reply will, to Status</li> </ul>	, and applicable to the second	to arms 2 tool.
1) Responsive to communication(s) filed on <u>09 F</u>	<u>ebruary 1998</u> .	
24/	is action is non-final.	
3) Since this application is in condition for allowa closed in accordance with the practice under the second secon	ance except for formal matte Ex parte Quayle, 1935 C.D.	rs, prosecution as to the merits is 11, 453 O.G. 213.
Disposition of Claims		
4)⊠ Claim(s) <u>1-18</u> is/are pending in the application		
4a) Of the above claim(s) is/are withdra		
5) Claim(s) is/are allowed.		
6) Claim(s) is/are rejected.		
7) Claim(s) is/are objected to.		
8)⊠ Claims <u>1-18</u> are subject to restriction and/or e	election requirement.	
Application Papers		
9) The specification is objected to by the Examine	er.	
10) The drawing(s) filed on is/are objected t		
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved		
12) The oath or declaration is objected to by the E	•	
,		
Priority under 35 U.S.C. § 119  13)	) priority under 35 U.S.C. & 1	119(a)-(d).
,		
a) ☐ All b) ☐ Some * c) ☐ None of the CERTIF	יבי טטאופא טו נוופ priority do	Jamento Have bodii.
1. received.	e / Serial Number	
2. received in Application No. (Series Cod		eau (PCT Rule 17 2/a))
3. received in this National Stage application		
* See the attached detailed Office action for a list		
14) Acknowledgement is made of a claim for dome	estic priority under 35 U.S.C	. & 119(е).
Attachment(s)		
14) Notice of References Cited (PTO-892) 15) Notice of Draftsperson's Patent Drawing Review (PTO-948) 16) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	18) Notice of In	Summary (PTO-413) Paper No(s)  Informal Patent Application (PTO-152)  Sice to Comply with Sequence Rules .

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#### **DETAILED ACTION**

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

### Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10, 12 and 15-18, drawn to an antibody that binds Apo-2, classified in class 530, subclass 388.22.
  - II. Claim 11, drawn to nucleic acid, classified in class 536, subclass 23.1.
  - III. Claim14, drawn to method of inducing apoptosis, classified in class 424, subclass 143.1.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acid of Invention II is related to the antibody of Invention I by virtue of encoding the same. The nucleic acid molecule has utility for the recombinant production of the antibody in a host cell. Although the nucleic acid molecule and antibody are related since the nucleic acid encodes the specifically claimed protein, they are distinct inventions the antibody product can be made by another and materially different process, such as by purification from a natural source.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case the antibody can be used in a materially different process such

§ 806.05(h)). In the instant case the antibody can be used in a materially different process such as in the immunoaffinity purification of the Apo-2 protein.

Inventions II and III are related in that the nucleic acid of II can encode the antibody used in the process of Invention III. However, the nucleic acid itself cannot be used in the process and the antibody encoded by the nucleic acid can be used in a process materially different from the process of Invention III, such as in the immunoaffinity purification of its cognate antigen.

- 2. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the search for one invention is not coextensive with another, and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 3. A telephone call was made to Diane L. Marschang on May 19, 1999 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## Sequences

5. This application contains sequence disclosures that are encompassed by the definitions for nucleic and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth in the attached Notice to Comply with Requirements for Patent Applications Containing Nucleic Sequence and/or Amino Acid Sequence Disclosures. In the current application, a CRF is required, but not none was submitted.

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- 6. According to 37 CFR 1.821(d) (MPEP § 2422), where the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the assigned identifier, in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application. The description refers to sequences of figures, but must instead refer to appropriate SEQ ID NO.
- 7. When a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and a sequence identifier ("SEQ ID NO:X") must be used either in the drawing or in the Brief Description of the Drawings. See MPEP § 2422.02. In the instant application, a sequence identifier must be used for the sequences appearing in Figures 1 and 2A-B.

Appropriate correction is required.

#### Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Friday from 8:00AM to 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED

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so as to avoid the processing of duplicate papers in the Office. Please advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.

Clair M. Ka

Patent Examiner, Art Unit 1646

May 24, 1999